

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10201

DEFENSE MEDICAL PURCHASE DESCRIPTION		NUMBER	DATE
		1	26 August 1971
FEDERAL STOCK NO.	ITEM IDENTIFICATION	POTENCY	UNIT
6505-159-4892	CLINDAMYCIN HYDROCHLORIDE HYDRATE CAPSULES, Equivalent to 150 mg of Clindamycin, 100s	24 Months	Bottle

1. SCOPE

1.1 This purchase description covers Clindamycin Hydrochloride Hydrate Capsules, Equivalent to 150 mg of Clindamycin.

2. APPLICABLE DOCUMENTS

2.1 Specifications and standards. Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposals of the specifications and standards referenced in the body of this specification shall apply to the extent specified herein. These documents may be obtained as directed by the contracting officer.

3. REQUIREMENTS

3.1 Material. Shall be Clindamycin Hydrochloride Hydrate Capsules, equivalent to 150 mg of clindamycin Base. Shall be suitable for use as an antibiotic.

Shall conform to the applicable regulations for the Certification of Antibiotics and Antibiotic-Containing Drugs as promulgated by the Food and Drug Administration, U. S. Department of Health, Education, and Welfare. Each lot shall be certified by the F.D.A. In addition to complying with the F.D.A. regulations, the finished capsules shall comply with the following requirements:

3.1.1 Assay. The capsules shall assay to contain not less than 90.0 percent and not more than 120.0 percent of the required amount of Lincomycin, when assayed in accordance with the applicable F.D.A. procedure.

3.1.2 Weight variation. The finished capsules shall comply with the requirements of the U.S.P. Weight Variation Test for Capsules.

3.1.3 Identification. The retention time of the clindamycin peak of the sample preparation in the assay is identical, within experimental error, to that of the Clindamycin Hydrochloride Hydrate Reference Solution.

3.1.4 Filled capsules. The filled capsules shall be uniform and free from manufacturing or other defects, such as, cracks, dents, splits, specks, etc.

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